

REMARKS/ARGUMENTS

Claims 1-14 are pending. Claims 15-17 have been added.

Claim rejections under 35 USC § 103

The Office Action dated 10/16/2009 rejected claims 1-14 under 35 U.S.C. 103(a) as being unpatentable over Katzberg et al. (US 6,122,540) in view of Unger (US 6,071,494). This rejection is respectfully traversed in view of the attached declaration by Prof. F. Graham Sommer, the inventor and applicant of the present application, submitted under 37 CFR §1.132 and the remarks presented herein.

The Office Action combines Katzberg, which discloses a magnetic resonance imaging (MRI) method of in-vivo measurement of renal hemodynamic functions (Katzberg Abstract), with Unger, which primarily discloses an ultrasound imaging method with enhanced contrast (Unger Abstract) although other imaging methods are discussed in general. The Office Action states that it would have been obvious to combine the MRI method of Katzberg with the analysis techniques and contrast agents in Unger to provide a computed tomography (CT) analysis of renal function as claimed in the present application. As asserted in the attached §1.132 declaration, it is respectfully submitted that the application's claimed invention is not obvious in view of the combination of Katzberg and Unger, as the imaging methods and contrast agents, and the mechanisms by which they operate, taught by the two references are completely different and not directly combinable. In particular, Unger does not teach the use of the para-magnetic MRI contrast agent Gd-DTPA of Katzberg as a radiographic CT agent as stated in the Office Action, and there is no motivation to use Gd-DTPA with CT methodology to measure renal function. While both MRI and CT are diagnostic imaging methods, the CT method claimed in the application is not obvious in view of the MRI method disclosed in Katzberg using the teachings of Unger.

Claims 1 and 10 recite obtaining CT numbers using a **radiographic** contrast agent to measure renal function. As detailed in the attached §1.132 declaration, Katzberg teaches the compound Gd-DTPA used as an MRI **para-magnetic** contrast agent, which alters T1 relaxation times in a series of magnetic resonance images. While Unger also teaches Gd-DTPA as an MRI para-magnetic contrast agent, Unger does not recommend Gd-DTPA as an MRI contrast agent for measuring blood flow due to low sensitivity at normal levels and toxicity at higher levels

(Unger Col. 3:66-4:25). Unger also does not teach using Gd-DTPA as a radiographic contrast agent for CT imaging, as asserted in the Office Action, nor does Unger connect Gd-DTPA to HU levels in CT image intensity. The Office Action cited sections of Unger (Col. 10:5-11:15 and Col. 12:25-13:13) that disclose using contrast agents for imaging in general and ultrasound imaging in particular with gaseous contrast agents for measuring blood flow; however, the sections cited do not teach Gd-DTPA for CT. Thus it is respectfully submitted that it is not obvious to combine the teachings of Unger with Katzberg to render obvious the limitations required by claims 1 and 10 and that claims 1 and 10 are patentable over the prior art of record.

In addition to the limitations required by independent claim 1, dependent claims 3 and 17 of the application recite **differences between CT numbers** (i.e. differences between CT image intensities) to measure the renal function. Calculating a difference of measured MRI image intensities as used in Katzberg would not provide meaningful results about renal function as described in the attached §1.132 declaration. As illustrated by the sole Figure in Katzberg, for some inversion times the venous image intensity is higher than the arterial image intensity, and for other inversion times the situation is reversed with the arterial image intensity higher than the venous image intensity. Instead of measuring differences in image intensity, Katzberg measures a change in T1 relaxation time using a time series of MRI images at a particular location. Measured data is fit to exponential curves to derive estimated T1 relaxation values (Katzberg Col. 3:65-67). Katzberg then teaches calculating a renal filtration fraction from estimated T1 relaxation times using Equation (5) (Katzberg Col. 3:5-20, 3:67-4:3). Thus Katzberg discloses measuring a **change in MRI image intensity** at a particular location **over time**. Katzberg does not disclose measuring differences in MRI image intensities or suggest such measurements for CT imaging. There is no motivation to conclude from Katzberg that renal function can be measured using differences in CT number image intensities in a set of CT images as required by claims 3 and 17. Unger does not disclose using differences in CT numbers to measure renal function either, and the Office Action did not state how the combination of Unger and Katzberg teaches the limitations recited in claim 3 and 17. It is respectfully submitted that claims 3 and 17 are patentable over the prior art of record.

In addition to all of the limitations of claim 1 discussed above, newly added dependent claim 15 of the application also requires calculating CT numbers as a mean value of image intensity for a plurality of voxels in **different locations** in one or more axial CT scans. Paragraph [0011] of the application provides support for this limitation of claim 15. In contrast, as

described in the attached §1.132 declaration, Katzberg discloses measuring a change in MRI image intensity **at a particular location** over time (Katzberg Col. 3:38-39). Katzberg teaches a transient measurement, while claim 15 recites an average measurement. It is respectfully submitted that neither Katzberg nor Unger, alone or in combination, teach the limitations recited in claim 15 and that claim 15 is patentable over the prior art of record.

Claims 2-9, 11-14 and 15-17 depend directly or indirectly from either independent claim 1 or independent claim 10. In addition, these claims add additional features, which taken together with the limitations of their associated independent claim are not anticipated or made obvious by the cited prior art references. For at least the reasons stated above for the independent claims, claims 2-9, 11-14 and 15-17 are respectfully submitted to be patentable over the prior art of record.

Applicants believe that all pending claims are allowable and respectfully request a Notice of Allowance for this application from the Examiner. Should the Examiner believe that a telephone conference would expedite the prosecution of this application, the undersigned can be reached at telephone number (408) 255-8001.

Respectfully submitted,
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